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| 10/517,274      | 12/09/2004 |            | Eran Schenker        | 26442U              | 4306             |
| 20529           | 7590       | 07/10/2006 |                      | EXAMINER            |                  |
| NATH & A        | SSOCIA     | TES        | TRIEU, VAN THANH     |                     |                  |
| 112 South W     | est Street | :          |                      |                     |                  |
| Alexandria,     | VA 223     | 14         |                      | ART UNIT            | PAPER NUMBER     |
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Please find below and/or attached an Office communication concerning this application or proceeding.

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|--|---|---|---|----------|
|  |   | Application No.   | Applicant(s)  |          |
|  |   | 10/517,274  | SCHENKER, ERAN  |          |
|  | Office Action Summary   | Examiner  | Art Unit  |          |
|  |   | Van T. Trieu  | 2612  |          |
| Period fo  | The MAILING DATE of this communication app<br>or Reply  | pears on the cover sheet with the o   | correspondence address  |          |
| WHIC<br>- Exte<br>after<br>- If NC<br>- Failu<br>Any | CORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATES IN THE MAILING THE | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). |          |
| Status   |   |   |   |          |
| 1)⊠  | Responsive to communication(s) filed on <u>09 De</u>  | <u>ecember 2004</u> .   |   |          |
| ′=   | <i>,</i> —  | action is non-final.  |   |          |
| 3)   | Since this application is in condition for allowar  | ,   |   |          |
|  | closed in accordance with the practice under E  | x parte Quayle, 1935 C.D. 11, 4   | 53 O.G. 213.  |          |
| Disposit   | ion of Claims   |   |   |          |
| 5) <u>□</u><br>6)⊠                                   | Claim(s) <u>1-55</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdray  Claim(s) is/are allowed.  Claim(s) <u>1-55</u> is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or   | wn from consideration.  |   |          |
| Applicat   | ion Papers  |   |   |          |
| 10)  | The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner The oath or declaration is objected to by the Examiner The specification is objected to be specification.   | epted or b) objected to by the drawing(s) be held in abeyance. Seion is required if the drawing(s) is ob  | e 37 CFR 1.85(a).<br>jected to. See 37 CFR 1.121(d).                        |          |
| Priority ι   | under 35 U.S.C. § 119   |   |   |          |
| 12) [<br>a)  | Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the priority application from the International Bureau  See the attached detailed Office action for a list of  | s have been received.<br>s have been received in Applicati<br>rity documents have been receive<br>u (PCT Rule 17.2(a)).   | ion No<br>ed in this National Stage   |          |
| 2) 🔲 Notic<br>3) 🔯 Infor                             | the of References Cited (PTO-892) the of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  |   |   |          |
|  | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date 12/9/04 & 7/11/05.  | 5)  Notice of Informal F<br>6)  Other:  | atent Application (PTO-152)   |          |

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### **DETAILED ACTION**

## Specification

1. The abstract of the disclosure is objected to because the PCT abstract.

Correction is required. See MPEP § 608.01(b).

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 2. Claims 1-12, 15-32 and 35-55 are rejected under 35 U.S.C. 102(e) as being anticipated by **Bui et al** [US 6,830,549].

Regarding claim 1, the claimed life detector adapted to be used to determine whether an organism or part thereof suits a life condition predefined by a set of ranges, each for a physiological parameter and each characterizing the life condition (the patient/user home management system 10, see Fig. 1, col. 2, lines 62-67 and col. 3, lines 1-7); and the detector comprising a sensor unit adapted to sense at least two of the physiological parameters and to generate signals indicative of their values (the physiological sensors 214, 215, 216 and 217, see Figs. 1 and 3A, col. 6, lines 4-12); and the processor for receiving and processing the signals to arrive at the values, the processor further being

adapted to disregard any value falling outside the range of the respective parameter and to produce a qualitative diagnosis based on values falling within its range, the diagnosis being indicative of whether the organism or part thereof suits the life condition, the detector further comprising indication means adapted to indicate the diagnosis (the microcontroller 201, see Figs. 3A and 3B, col. 3, lines 54-61, col. 9, lines 46-67, col. 10, lines 1-62 and col. 16, lines 55-65).

Regarding claim 2, the claimed range of each of the at east two parameters includes a predefined set of sub-ranges, each characterizing a particular state within the life condition and each having a predefined priority level with respect to the life condition, the processor being further adapted to determine the particular sub-range in which the value of each parameter falls and the state characterized by the sub-range, and to produce a qualitative diagnosis based only on the state having the highest priority level (the priorities, see col. 20, lines 51-67, col. 21, lines 1-7 and col. 22, lines 33-49).

Regarding claim 3, the claimed detector is adapted to be used by a human operator (the patient/user 300, see Fig. 2).

Regarding claim 4, the claimed indication means is adapted to indicate the diagnosis to a human operator (the display 114, lamps 118, LCD display 219 and speaker 116, see Figs. 3B and 4, col. 8, lines 1-4).

Regarding claim 5, the claimed organism is a human or an animal and the life condition is health condition (patient/user 300, see Fig. 2).

Regarding claim 6, the claimed at least two parameters are any two of the following: pulse rate, blood oxygen saturation level, and temperature, see col. 16, lines 55-60).

Regarding claim 7, the claimed detector is adapted to be use by a human operator, the processor and the indicator means being adapted to indicate the diagnosis to such human operator who is not a medical professional (the patient/user 300 carrying the physiological monitor 20 is not a medical professor, see Fig. 2).

Regarding claim 8, the claimed organism is a microorganism, and the life condition is being alive, which reads upon the patient's microorganism such as blood cells and/or microorganism bacteria in the blood causing raising temperature being sensed by sensors 215, 217, 53 and 54, see Fig. 2, col. 6, lines 3-32 and col. 11, lines 21-25.

Regarding claim 9, the claimed at least two parameters are any two of the following: fluorescence, reflected light, gas discharge, temperature, and pulsatile behavior (the gas discharge 53 and pulse oximetry sensor 214, see Figs. 1-3, col. 6, lines 3-67 and col. 7, lines 1-6).

Regarding claim 10, the claimed organism is of astrobiology type, and the life condition is being alive, which reads upon the patient's body organism being monitored by the gas discharge 53 and pulse oximetry sensor 214, and temperature sensor 217 see Figs. 1-3, col. 6, lines 3-67 and col. 7, lines 1-6).

Regarding claim 11, the claimed at least two parameters are any two of the following: gas discharge, temperature, and pulsatile behavior (the gas discharge 53 and pulse oximetry sensor 214 and temperature sensor 217, see Figs. 1-3, col. 6, lines 3-67 and col. 7, lines 1-6).

Regarding claim 12, the claimed sensor unit is adapted to sense the physiological parameters by directly contacting the body of the human or animal (the sensors 214, 215, 216, and 217, see Fig. 3).

Regarding claim 15, the claimed sensor unit comprises an electrocardiograph (the ECG 217A, 217B and 217C, see Fig. 2, see col. 6, line 67 and col. 7, lines 1-2).

Regarding claim16, the claimed a rod with the sensor unit attached thereto (see Figs. 21A and 21B).

Regarding claim 17, the claimed rod is tubular (see Figs 21A and 21B).

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Regarding claim 18, the claimed rod is adapted to changes its length (the length of temperature sensor 216 could be changed of cable 322, see Figs. 21A and 21B).

Regarding claim 19, the claimed rod is adapted to be operatively and reversibly bent (the cable 322 can be bent, see Figs. 21A and 21B).

Regarding claim 20, the claimed detector is in the form of a hand-held unit, see Figs. 2 and 4

Regarding claim 21, the claimed detector is in the form of a flexible cable with the sensor unit attached to one end of the cable, see Fig. 2.

Regarding claim 22, the claimed processor and the indication means are further adapted to indicate the values (the monitor 20, see Figs. 3B and 4).

Regarding claim 23, the claimed indication means comprises at least one of the following: a visual display, an audio indicator, and a vibration indicator (see Figs. 3B and 4).

Regarding claim 24, the claimed a communication means adapted to transmit at least the diagnosis to a remote location (the communication unit 30, see Figs. 1-3, col. 6, lines 13-62 and col. 7, lines 1-65).

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Regarding claim 25, the claimed processor and the indication means are united in a single device (the monitor 20 includes a microcontroller 201 and display LCD 219 and speaker 220, see Figs. 3B and 4).

Regarding claim 26, the claimed single device comprises a communication means adapted to transmit the diagnosis to a remote location (the single communication unit 30, see Figs. 1-3).

Regarding claim 27, the claimed single device is a programmable cellular phone or a palm-top computer (the programmable monitor 20, see Figs. 3 and 4, col. 3, lines 1-30 and col. 6, lines 64-65).

Regarding claim 28, the claimed single device is a general-purpose programmable device (PD), the sensor unit comprises a standard medical sensor, the life detector further comprises a cable adapter interfacing the programmable device to the medical sensor, and a driver program specifically directed to use with the medical sensor, the cable adapter and the PD is loaded in the PD (the programmable monitor 20 having a plurality of sensors 214, 215, 216 and 217 connected via cables, see Figs. 1-3).

Regarding claim 29, the claimed programmable device has remote communication capability, see Figs. 1-3.

Regarding claim 30, the claimed cable detector for use with the life detector, see Figs. 2, 3, 21A and 21B.

Regarding claim 31, the claimed interfacing includes maintaining correct input and output voltages and scaling of signal data between the PD and the medical sensor (the interface circuits 212, 213 and scale 58, see Figs. 1 and 3A, col. 13, lines 43-67 and col. 14, lines 1-24).

Regarding claim 32, the claimed interfacing includes providing electric power from the PD to the medical sensor (the line power, see col. 13, lines 53-67 and col. 14, lines 1-24).

Regarding claim 35, the claimed at least one audio aid of the following: voice microphone, speaker, sound detector, headphones (the communication unit 30 communicates voice messages over the telephone line, see Figs. 1, 3A and 3B, col. 7, lines 27-34, col. 12, lines 42-45 and col. 13, lines 5-23).

Regarding claim 36, the claimed sensor unit is adapted for prolonged association with the organism while the detector is adapted for repeated or continuous production and indication of the diagnosis, thereby providing monitoring of the life condition, see col. 2, lines 31-36 and col. 3, lines 32-61).

Regarding claim 37, the claimed at least one of the sensor unit and the indication means is detachable from the detector and adapted for remote communication with the detector so that an operator of the detector could perform the monitoring remotely (the remote carrier is received the detected data and alarm signals and to provide instructions for controlling and operating of the monitor unit 20, see Figs. 1, 3 and 5, col. 4, lines 38-67, col. 5, lines 1-15, col. 6, lines 39-67, col. 7, lines 1-59 and col. 8, lines 1-65).

Regarding claim 38, the claimed further adapted to treat the organism (the patient home management system 10 is for remotely monitoring and controlling of a medical treatment device being connected with the sensors and infusion pump, see col. 1, lines 43-65 and col. 6, lines 34-38).

Regarding claim 39, the claimed at least one of the following means for treatment:: gas supply line, liquid supply line, suction line, power electric line, and mechanical manipulators (controlling the infusion pump for treatment, see Figs. 1-3, col. 3, lines 32-38, col. 4, lines 28-65 and col. 6, lines 34-38).

Regarding claim 40, the claimed sensor unit comprises a permanent base and at least one changeable sensor module detachably attachable to the base (the permanent base

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respiration sensor 215 and ECG sensor 217; and the changeable core temperature sensor 216, oximeter 216 and infusion pump, see Figs. 1-3, col. 6, lines 2-38).

Regarding claim 41, the claimed at least one changeable treatment module detachably attachable to the base (the infusion pump is changeable, see col. 6, lines 34-38).

Regarding claim 42, the claimed based and the changeable modules have identical means for attachment so that the changeable modules are interchangeable among themselves, which reads upon the physiological sensors 214, 215, 216, 217 and infusion pump can be interchanged themselves.

Regarding claim 43, the claimed at least one dummy module, which is interchangeable with anyone of the sensor and treatment modules, which reads upon the infusion pump).

Regarding claim 44, the method claimed limitations are met by the apparatus claim 1 above.

Regarding claim 45, all the claimed subject matters are cited in respect to claim 1 above.

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Regarding claim 46, all the claimed subject matters are cited in respect to claims 1 and 28 above.

Regarding claim 47, all the claimed subject matters are cited in respect to claims 31 and 46 above.

Regarding claim 48, all the claimed subject matters are cited in respect to claims 32 and 46 above.

Regarding claim 49, all the claimed subject matters are cited in respect to claims 37 and 46 above.

Regarding claim 50, the claimed plurality of different medical sensors and/or with a plurality of different PDs (the different physiological sensors 214, 215, 216, 217, 53, 54, 56, 58 and 59, see Figs. 1-3).

Regarding claim 51, all the claimed subject matters are cited in respect to claims 1,28 and 46 above.

Regarding claim 52, all the claimed subject matters are cited in respect to claim 31 and 51 above.

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Regarding claim 53, all the claimed subject matters are cited in respect to claim 32 and 51 above.

Regarding claim 54, all the claimed subject matters are cited in respect to claim 37 and 51 above.

Regarding claim 55, all the claimed subject matters are cited in respect to claim 50 and 51 above.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 13, 14, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bui et al** [US 6,830,549] in view of **Abreu** [US 7,041,063] Regarding claim 13, **Bui et al** fails to disclose the sensor unit comprises an optical sensor. However, **Bui et al** teaches that the physiological sensors such as a pulse oximetry sensor 214 and a thermo sensor 217 for detecting and measuring the core temperature of a patient 300, see Figs. 1-3, col. 6, lines 3-12. **Abreu** suggests that, oxygenated hemoglobin has been measured non-invasively. The so called pulse oximeter is based on traditional near infrared absorption spectroscopy and indirectly

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measures arterial blood oxygen with sensors placed over the skin utilizing LEDs emitting at two wave lengths around 940 and 660 nanometers. As the blood oxygenation changes, the ratio of the light transmitted by the two frequencies changes indicating the amount of oxygenated hemoglobin in the arterial blood of the finger tip. The present systems are not accurate and provide only the amount of oxygenated hemoglobin in the finger tip. The same principles disclosed above can be used for near-infrared transmission measurements as well as for continuous wave tissue oximeters, evaluation of hematocrit and other blood components. The substance of interest can be endogenous such as glucose or exogenous such as drugs including photosensitizing drugs. It is understood that any electrochemical sensor, thermoelectric sensors, acoustic sensors, piezoelectric sensors, optical sensors 48, 50, and the like can be mounted in the contact device and placed on the surface of the eye for detection and measurement of blood components and physical parameters found in the eye with signals preferably transmitted to a remote station. It is understood that electrochemical sensors using amperometric, potentiometric, conductometric, gravimetric, impedimetric, systems, and the like can be used in the apparatus of the invention for detection and measurement of blood components and physical parameters such as core temperature found in the eye with signals preferably transmitted to a remote station, see Fig. 1, col. Col. 6, lines 52-62, col. 36, lines 5-17, col. 62, lines 34-67 and col. 165, lines 8-13. Therefore, an artisan would substitute the optical sensor of **Abreu** for the oximeter and/or core temperature sensors of **Bui et al** since any thermoelectric sensors, acoustic

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sensors and/or optical sensors are used to detect the oxygen in the blood and core temperature of a body.

Regarding claim 14, the claimed optical sensor is a reflectance pulse SpO2 oximeter, is met by the combination of optical sensor between **Bui et al** and **Abreu** in respect to claim 13 above.

Regarding claim 33, Bui et al fails to disclose the means for determining the location of the organism. However, Bui et al teaches that the monitor unit 20 for receiving detected signals from a pulse oximetry sensor 214 and a thermo sensor 217 for detecting and measuring the core temperature of a patient 300, see Figs. 1-3, col. 6, lines 3-12. Jeffrey et al suggests that microorganisms in specimens of body fluids, such as blood, containing as few as 1 organism per total sample volume, can be detected using this invention. Such specimens may require a number of days of incubation before the population of organisms reaches a critical level and where a change in a parameter involved in microorganism metabolism can be measured. The instrument provides a controlled environment for incubating plates, which can include a heater if incubation is to take place at an elevated temperature from ambient (though an elevated temperature is not necessary in all situations). A fluid sample is added to the sensor plate device, after which the sensor plate is placed in the instrument where it is subsequently sensed/observed by an image acquisition/capture device (e.g. a camera or scanner) during the incubation period. Images of the bottom of the sensor plate

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device can be captured at regular predetermined intervals and subsequently analyzed using one or more image processing techniques and algorithms to determine whether a microorganism colony is present on the sensor plate, see Fig. 1, col. 2, lines 5-34, col. 4, lines 9-15, col. 9, lines 59-67 and col. 10, lines 1-7. Therefore, artisan would substitute the sensor and instrument for determining location of the microorganism on the sensor of **Jeffrey et al** for the sensor and monitor unit of **Bui et al** for providing location of the sensed blood data signals since the sensors are designed to detect blood stream in a body.

Regarding claim 34, **Bui et al** fails to disclose the means for determining the location is at least one of the following: a video camera, a thermal camera, a light source.

However, according to the combination of the location determination combined between **Bui et al** and **Jeffrey et al** in respect to claim 33 above, and further **Jeffrey et al** teaches that the instrument includes a camera or scanner are adapted to capture the image of the microorganism location, see col. 9, lines 59-67 and col. 10, lines 1-7.

### Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

**Lebel et al** discloses an implantable infusion pump controlled by software operating in two processor ICs and with plurality of physiological sensors. The implant infusion pump is communicating with an external subsystem for displaying and alarming of the results. [US 6,873,268]

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**Jung et al** discloses an optical characteristic measuring systems and methods for determining the color or other optical characteristics of teeth. [US 6,118,521]

5. Any inquiry concerning this communication or earlier communications from examiner should be directed to primary examiner **Van Trieu** whose telephone number is (571) 272-2972. The examiner can normally be reached on Mon-Fri from 7:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Mr. Mike Horabik** can be reached on (571) 272-3068.

Wan Trieu

**Primary Examiner** 

Date: 7/6/06